

Notice of Allowability

Application No.

09/966,515

Examiner

Frank W Lu

Applicant(s)

KOPRESKI, MICHAEL S.

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments filed on 2/25/2003 and 4/15/2003, and terminal disclaimer filed on 2/25/2003.
2. ☒ The allowed claim(s) is/are 1-12, 21, 35-41, 52 and 53.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>4/03</u> . |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>4/03</u> . | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

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REASONS FOR ALLOWANCE

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Kevin Noonan (Reg. No.35,303) on April 15, 2003.

2. The application has been amended as follows:

Cancel claims 13-20, 22-34, 42-45, and 47-50.

Delete "a RNA" in line 2 of claims 3 and 4 and replace with "an".

Add "or" before the phrase "labeled fluorescent or chromagenic probes" in claims 5 and

6.

Renumber claim 36 in the amendment filed on February 25, 2003 as claim 35.

Renumber claim 37 in the amendment filed on February 25, 2003 and April 15, 2003 as claim 36.

Delete "mammalian" in line 1 of claim 35.

Delete "(erb-B-1)" in line 6 of claim 35.

Add the phrase "a non-cellular fraction of " before the phrase "a bodily fluid" in claim 37.

Delete "cDNA" in line 1 of claims 52 and 53 and replace with " a cDNA".

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Delete "cDNA corresponding to said RNA" in last line of claims 52 and 53 and replace with "the cDNA corresponding to one of epidermal growth factor RNA, epidermal growth factor receptor RNA, her-2/neu RNA, c-myc RNA, and heterogeneous nuclear A2/B1 RNA".

3. The following is an examiner's statement of reasons for allowance:

Claims 1-12, 21, 35-41, 52, and 53 are allowable in light of the applicant's amendments and terminal disclaimer, applicant arguments (see pages 8 and 9 of applicant's remarks filed on April 15, 2003) and the examiner's amendments. The closest prior art in the record are Kopreski *et al.*, (Clin. Cancer Res., 5, 1961-1965, August 1999), Leitzel *et al.*, (Clin. Cancer Res., 4, 3037-3043, December 1998), Zhou *et al.*, (J. Biol. Chem., 271, 10760-10766, May 1996) and Burd *et al.*, (Proc. Natl. Acad. Sci. USA, 86, 9788-9792, 1989). These prior art either alone or in combination with the other art in the record does not teach or reasonably suggest a method for detecting tumor-derived or tumor-associated RNA in the plasma or serum fraction of blood from a human or animal, a method for detecting extracellular tumor-derived or tumor-associated RNA in a non-cellular fraction of a bodily fluid from a human or animal, a method for monitoring an animal or human for a malignant or premalignant disease, a method for selecting an animal or human with cancer for a cancer-directed therapy, and a method for producing cDNA by reverse transcription of a fraction of extracellular total RNA extracted from plasma or serum from human or animal which comprise all of the limitations recited in claims 1, 2, 21, 35, 52, and 53.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu whose telephone number is (703) -305-1270.

Frank Lu
April 16, 2003



Ethan Whisenant, Ph.D.
Primary Examiner (FSA)